



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0154; FRL-9648-01-OCSP]

Cyantraniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of cyantraniliprole in or on sugarcane, cane. Syngenta Crop Protection, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0154, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744.

Due to the public emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-2659; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

To access the OCSPP test guidelines referenced in this document electronically, please go to <https://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in

40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0154 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0154, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of April 22, 2021 (86 FR 21317) (FRL-10022-59), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F8868) by Syngenta Crop Protection, LLC, P.O. Box 18300

Greensboro, NC 27419. The petition requested that 40 CFR 180.672 be amended by establishing a tolerance for inadvertent residues of the insecticide, cyantraniliprole, 3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[(methylamino)carbonyl] phenyl]-1H-pyrazole-5-carboxamide in or on sugarcane at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket (EPA-HQ-OPP-2021-0154), <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the commodity definition for sugarcane. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyantraniliprole including exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with cyantraniliprole follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking. EPA has previously published tolerance rulemakings for cyantraniliprole in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to cyantraniliprole and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological Profile. For a discussion of the Toxicological Profile of cyantraniliprole, see Unit III.A of the cyantraniliprole tolerance rulemaking published in the *Federal Register* of November 13, 2018, 83 FR 56262 (FRL-9985-32).

Toxicological Points of Departure/Levels of Concern. For a discussion of the Toxicological Points of Departure/Levels of Concern used for the safety assessment of cyantraniliprole, see Unit III.B of the February 5, 2014, rulemaking (79 FR 5826) (FRL-9388-7).

Exposure Assessment. Much of the exposure assessment for cyantraniliprole remains unchanged from the discussion in Unit III.C of the November 13, 2018, rulemaking, except as described below.

EPA's current exposure assessment has been updated to include the additional exposure from this petitioned-for tolerance for residues of cyantraniliprole on sugarcane. The rotational crop use does not result in an increase in the estimated residue levels in drinking water or in exposure from residential sources relative to those used in the last assessment. EPA's aggregate exposure assessment incorporated this additional dietary exposure, as well as exposure from drinking water and from residential sources. There are no changes to EPA's conclusions in the

November 13, 2018, rulemaking concerning cumulative effects.

Safety Factor for Infants and Children. EPA continues to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the Food Quality Protection Act (FQPA) safety factor were reduced from 10X to 1X. The reasons for that decision are articulated in Unit III.D of the November 13, 2018, rulemaking.

Assessment of aggregate risks. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Acute dietary risks are below the Agency's level of concern. Since no effects of concern have been identified for cyantraniliprole resulting from 1-day or single exposures, a qualitative acute dietary exposure assessment is unnecessary. Chronic dietary risks are likewise below the Agency's level of concern: 64% of the cPAD for all infants (<1 year old), the group with the highest exposure. EPA has concluded the combined short-term food, water, and residential exposures result in aggregate margins of exposure above the level of concern of 100 for all scenarios assessed and are not of concern. All risk estimates for intermediate-term aggregate risk are not of concern. An aggregate cancer risk assessment was not conducted because cyantraniliprole is not considered to be a carcinogen. The chronic aggregate assessment did not result in risk estimates of concern.

Determination of safety. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cyantraniliprole residues.

Further information about EPA's risk assessment and determination of safety supporting the new cyantraniliprole tolerance can be found at <https://www.regulations.gov> in the document

titled “Cyantraniliprole. Human Health Risk Assessment for an Inadvertent Tolerance on Sugarcane” in docket ID EPA-HQ-OPP-2021-0154.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass spectroscopy (LC/MS/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

There are no Codex MRLs established for residues of cyantraniliprole on sugarcane.

C. Response to Comments

EPA received one comment in response to the April 22, 2021, notice of filing. The comment seems to express general concern about pesticides, and specifically requests that EPA not permit the use of “cyanide”—a completely unrelated chemical—on “sugar”. No specific concerns about EPA’s current evaluation were raised. While the agency recognizes that some people oppose the use of pesticides in or on food commodities, the FFDCA allows EPA to establish tolerances for residues of pesticides in or on food as long as the Agency can determine those tolerances are safe. The Agency has evaluated the aggregate exposures of cyantraniliprole and has determined that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to cyantraniliprole residues. The

commenter has provided no information to support a conclusion that the tolerance is not safe.

D. Revisions to Petitioned-For Tolerances

The Agency is establishing a tolerance for the commodity “sugarcane, cane” rather than “sugarcane”, as requested, to be consistent with the food commodity nomenclature.

V. Conclusion

Therefore, a tolerance is established for inadvertent residues of cyantraniliprole in or on sugarcane, cane at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and

responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 31, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180 -- TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.672, the table in paragraph (d) is amended by:

a. Adding a table heading; and

b. Adding the commodity “Sugarcane, cane” to the table in alphabetical order.

The additions read as follows:

§180.672 Cyantraniliprole; tolerances for residues.

(d) * * *

Table 2 to Paragraph (d)

Commodity	Parts per million
* * * * *	*
Sugarcane, cane	0.01